GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:1933
ANSWERED ON:14.03.2017
Fixed Drugs Combinations
Sreeramulu Shri B.

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government has constituted an expert committee under the chairmanship of Prof. C.K. Kokate to frame guidelines for the approval and use of Fixed Drugs Combinations (FDC) across the country;

(b) if so, the details thereof;

(c) whether the Government has banned FDC medicines on the basis of Prof. C.K. Kokate Committee Report and if so, the list of FDC medicines banned in the country; and

(d) the steps taken/being taken by the Government so far to ensure marketing of only the approved FDC medicines to the public?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) & (b): An expert committee was constituted by Ministry of Health and Family Welfare under the Chairmanship of Prof. C. K. Kokate, Vice chancellor, KLE University, Belgaum vide order no. 12-01/12-DC (Pt. 133)/DFQC dated 06.02.2013 to formulate policy guidelines and procedures for approval of Fixed dose Combinations.

(c): Ministry of Health and Family Welfare vide order no. X.11035/53/2014-DFQC dated 16.09.2014 constituted an Expert Committee under the chairmanship of Prof. C. K. Kokate for examination of FDCs licensed to manufacture for sale in the country without due approval from office of DCG(I). On the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government prohibited the manufacture for sale, sale and distribution for

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human use of 344 drug fixed dose combination vide gazette notification no. S.O 705(E) to 1048(E) dated 10.03.2016. (List of 344 FDC medicines banned in the country is enclosed as Annexure A). However, various stakeholders filed various writ petitions in different High Courts across the country and the said notification was quashed by Hon'ble High Court of Delhi vide its order dated 01.12.2016. Further, the Union of India had already challenged the order of Delhi High Court before the Supreme Court by way of SLP. The same is yet to be listed.

(d): Directions under Section 33 (P) of Drugs & Cosmetics Act, 1940 were issued initially by the Central Government to Principal/ Health Secretaries of all state/ UTs on 20.07.2000 for not granting licences for manufacture for sale of drugs considered as New Drugs without prior approval of DCG(I). The last such statutory direction was issued by the Ministry vide letter No. X11011/1/2011-DFQC dated 1st October, 2012. The Drugs and Cosmetics Rules were also amended in 2002 to bring clarity that the applicant, while applying to State Licensing Authority for grant of manufacturing license for New drug shall submit approval from DCG(I) to manufacture the New drug.

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